

## REMARKS

The Office Action mailed October 22, 2002 has been received and reviewed. Claims 30-68 are currently pending in the application. Claims 33 and 68 have been withdrawn from consideration as assertedly being drawn to a non-elected invention. Claims 30-32 and 34-67 stand rejected. Applicants have amended claims 30-32, 34-35, 38-40, 43, 46-50, 53, 56, 59-63, 65 and 67 as set forth herein. All amendments are made without prejudice or disclaimer. Reconsideration is respectfully requested.

### **Election/Restrictions**

Claims 32, 34, 35, 47 and 59-63 have been amended such that they are directed to SEQ ID Nos: 1-7 in accordance with the election.

### **Objections to Claims**

Claims 39 and 49 were objected to for reciting "an" instead of "a." The claims have been amended in accordance with the suggestion of the Examiner. Withdrawal of the objections is requested.

### **Rejections under 35 U.S.C. § 101**

Claims 30-32 and 34 stand rejected under 35 U.S.C. § 101 as assertedly being directed to non-statutory subject matter. Applicants respectfully traverse the rejections.

Specifically, it was asserted that the claims 30-32 and 34 read on a nucleic acid sequence which is found in nature and unpatentable. Although applicants do not agree that the claims are directed to non-statutory subject matter, claims 30-32 and 34 have been amended to include the term "isolated" as suggested by the Examiner. Reconsideration and withdrawal of the rejections of claims 30-32 and 34 are requested.

### **Rejections under 35 U.S.C. § 112, second paragraph**

Claims 30-32 and 34-67 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite for failing to particularly point out and distinctly claim the subject

matter which applicants regard as the invention. In view of the amendments to the claims, applicants respectfully traverse the rejections.

Claims 30-32 and 34 were thought to be indefinite for use of the phrase “for use in cloning and expressing a root specific nucleic acid sequence.” Although applicants do not agree that the claims are indefinite, in order to expedite prosecution, claims 30-32 and 34 have been amended to recite “an isolated nucleic acid sequence which can be used for cloning a root specific nucleic acid sequence and which is able to direct a root selective expression of a coding nucleic acid sequence in a plant.”

When read in conjunction with the specification, amended claims 30-32 and 34 are believed to overcome the indefiniteness rejections since the phrase “root specific nucleic acid sequence” is defined on page 13 of the specification as “nucleic acid sequences, i.e. genes, coding sequences and/or regulatory elements which are exclusively or mainly active in roots of plants, in particular those which direct or contribute to a root abundant or root selective expression of a protein.” (Specification, page 13).

Claims 30-32 and 34 were further thought to be indefinite for reciting the term “alleles,” the phrase “alleles of the complementary sequence” and including other recitations regarding the alleles of complementary sequences. Although applicants do not agree the claims are indefinite, claims 30-32 and 34 have been amended to remove the elements of the claims relating to alleles to expedite prosecution. Thus, claims 30-32 and 34 should be definite.

Claims 38 and 48 were thought to be indefinite for use of the phrase “character of agronomic or industrial benefit.” To expedite prosecution, the term “character” has been replaced by the term “trait” as suggested by the Examiner. Accordingly, claims 38 and 48 should be definite.

The phrase, “which further includes regulatory elements directing or enhancing the expression of the gene of interest” was thought to render claims 40 and 50 indefinite. Claims 40 and 50 have been amended to recite in part “further including regulatory elements directing or enhancing the expression of the gene of interest.” As defined in the specification, “regulatory elements” refers to a sequence whose transcription and expression is controlled by the regulatory element. (*See, Specification, page 9*). Further, as known in the art, the activity of a promoter can

be increased by the presence of a regulatory element, *i.e.*, such as an enhancer sequence. Thus, amended claims 40 and 50 should be definite.

In claim 46, the phrase “in conjunction with” was thought to render the claim indefinite. Claim 46 has been amended to include the phrase “operably linked to” in accordance with the suggestion of the Examiner, thus, rendering claim 46 definite.

The recitation “or a plant having a host cell containing a vector comprising a nucleic acid” in claim 62 was thought to render the claim indefinite. The phrase “wherein the composition” has been included in claim 62 to more clearly recite that the composition of matter is derived from a plant having a host cell containing a vector. Thus, claim 62 is believed to be definite.

Claim 63 was thought to be indefinite for reciting “the vector” in the last line. The phrase “contained in the vector in” has been deleted from the last line of claim 63, rendering the claim definite.

In view of the amendments and remarks presented herein, reconsideration and withdrawal of the indefiniteness rejections of claims 30-32 and 34-67 are requested.

### **Rejections under 35 U.S.C. § 112, first paragraph**

#### Claims 30-32 and 34-67

Claims 30-32 and 34-67 stand rejected under 35 U.S.C. § 112, first paragraph, as assertedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors had possession of the claimed invention. Claims 30-32 and 34-67 were also rejected under 35 U.S.C. § 112, first paragraph, as assertedly lacking enablement for any nucleic sequence that differs from SEQ ID NOs: 1-7 and having root specific transcriptional activity. Applicants respectfully traverse the rejections as hereinafter set forth.

More particularly, it was thought that the specification does not describe or enable any nucleic acid sequence that has more than 70% identity with any of SEQ ID Nos. 1-7, alleles of SEQ ID Nos. 1-7, sequence having more than 70% identity to the alleles, the complements of the alleles, and alleles having more than 70% identity to the complements of SEQ ID Nos. 1-7. It

was further thought that the specification does not describe the sequences of SEQ ID Nos. 1-7 that can be changed without affecting its functional activity, other than the deletions of SEQ ID No. 1 that produced SEQ ID Nos. 1-7. Although applicants do not agree that the specification does not describe or enable the claimed invention, for the sake of expedited prosecution the claims have been amended to remove the language of the claims directed to the alleles of the various SEQ ID Nos.

The Office Action indicates “[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself.” (Office Action, page 7, *quoting Fiers v. Sugano*, 984 F.2d 1164, 25 USPQ2d 1601, (Fed. Cir. 1993)). The language of the amended claims meets this requirement since a concrete description of the DNA by way of “SEQ ID Nos. 1-7” is present in the claims and the various sequences are disclosed in the sequence listing. Therefore, the recitation of “having a degree of identity of more than 70%” to the various sequences is supported by a definite description of the nucleic acid.

The claims further recite that the sequences are able to direct a root selective expression of a coding nucleic acid sequence in a plant as a function of the sequence. Thus, since the claims are directed to a description of the nucleic acid sequence, *i.e.*, the sequence listing discloses the structure, wherein the nucleic acid sequence is able to direct a function of root selective expression of a coding nucleic acid sequence in a plant, a structure and function are claimed.

Accordingly, the specification reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention as required to satisfy the written description requirement and teaches one of ordinary skill in the art to practice the claimed invention without undue experimentation to satisfy the enablement requirement.

The Office Action further indicated that even minor changes in nucleotide sequence can alter the activity of the promoter. (*See, Office Action*, page 9, *citing Kim et al.*, *Plant Mol. Biol.*, 1994, Vol. 24, pages 105-117). However, the changes in the nucleotide sequence of Kim et al. occurred in a specific conserved region of 20 nucleotides in length of the *nos* promoter wherein the changes resulted in a loss of activity of the *nos* promoter. (*See, Kim et al.*, Abstract). The claimed sequences of the present invention have identities of more than 70% to various listed

sequences, wherein the claimed sequences retain the ability to direct a root selective expression of a coding nucleic acid sequence in a plant.

Further, one of skill in the art would be able to modify any of the sequences of SEQ ID Nos. 1-7 using known molecular techniques and be able to select the altered sequences that still possess the ability to direct a root selective expression of a coding nucleic acid sequence in a plant without undue experimentation. This is in accord with the disclosure of Croy et al. which states “[a] modified sequence may be obtained by introducing changes into an unmodified promoter sequence. This may be achieved by any appropriate technique ... Whether a part of the full length promoter sequence or a modified sequence is capable of acting as a promoter may be readily obtained by experiment.” (Croy et al., pages 4-5). Thus, one of skill in the art would be able to ascertain whether the modified nucleic acid sequences possess the required function without undue experimentation.

Accordingly, reconsideration and withdrawal of the rejections of claims 30-32 and 34-67 are requested.

Claims 47-57, 59, 63, 64, 66 and 67

Claims 47-57, 59, 63, 64, 66 and 67 stand rejected under 35 U.S.C. § 112, first paragraph, since the specification assertedly does not teach how to use non-plant host cells. Specifically, it was thought that SEQ ID Nos. 1-7 which are from a plant gene and direct transcription specifically in plant root tissue would not be obvious to use in other cells. Applicants respectfully traverse the rejections as hereinafter set forth.

As known in the art, *Agrobacterium tumefaciens* may be used to deliver DNA not only to dicotyledonous plants, but also to monocotyledonous plants, yeasts and fungi. “Applicant may submit factual affidavits under 37 CFR 1.132 or cite references to show what one skilled in the art knew at the time of filing the application.” (M.P.E.P. § 2164.05). Accordingly, applicants submit the attached references which demonstrate that DNA can be delivered to yeast and fungi using *Agrobacterium tumefaciens*. (See, de Groot et al., *Agrobacterium tumefaciens*-mediated transformation of filamentous fungi, Abstract, attached hereto; see also, Bundock et al., Integration of *Agrobacterium tumefaciens* T-DNA in the *Saccharomyces cerevisiae* genome by

illegitimate recombination, attached hereto). Reconsideration and withdrawal of the rejections of claims 47-57, 59, 63, 64, 66 and 67 are, thus, requested.

Claims 44-46 and 54-56

Claims 44-46 and 54-56 stand rejected under 35 U.S.C. § 112, first paragraph, since it was asserted to be unclear how one skilled in the art can use the claimed vectors comprising T-DNA which have only one of the T-DNA border sequences. Applicants respectfully traverse the rejections as hereinafter set forth.

Specifically, the Office Action indicated that “Walden (Meth. Plant Biochem., 1997, Vol. 10b, pages 65-83) teaches that the presence of the border sequences is required to both define and delimit the plasmid sequences which are transferred to the plant genome (page 67). It is then not clear, and taught by the specification, how one skilled in the art can use the claimed vectors comprising T-DNA which have only one of the T-DNA border sequences.” (Office Action, page 10).

Applicants respectfully submit that the Office is misinterpreting the teachings of Walden. As known in the art, the left border or the right border sequence of T-DNA can be used individually or together to integrate the nucleic acid into a genome. As stated in Croy et al. “[t]ypically the DNA to be integrated into the plant cell genome is delineated by the T-DNA border sequences of a Ti-plasmid. If only one border sequence is present, it is preferably the right border sequence.” (Croy et al., page 7, lines 15-18). From the recited passage, it should be apparent to one of ordinary skill in the art that only one border is required to integrate nucleic acid into the genome. Accordingly, reconsideration and withdrawal of the rejections of claims 44-46 and 54-56 are respectfully requested.

**Rejections under 35 U.S.C. § 102**

Claims 30-32, 34-38, 40-48 and 50-66 stand rejected under 35 U.S.C. § 102(b) as assertedly being anticipated by Croy et al. (WO 91/13992). Applicants respectfully traverse the rejections as hereinafter set forth.

Croy et al. relates to the promoter of the extensin gene of rape which is capable of directing protein expression in roots. The promoter disclosed in Croy et al. is depicted in FIG. 1 from -1616 to 1. (See, Croy et al., FIG. 1). Since the extA promoter of Croy et al. has a completely different sequence than any of the claimed sequences, *i.e.*, nucleic acids SEQ ID Nos. 1-7, nucleic acid sequences complementary to SEQ ID Nos. 1-7, or nucleic acid sequences having a degree of homology of more than 70% to SEQ ID Nos. 1-7 or the sequence complementary to SEQ ID Nos. 1-7, Croy et al. does not anticipate any of claims 30-32, 34-38, 40-48 and 50-66.

In view of the foregoing, reconsideration and withdrawal of the anticipation rejection of claims 30-32, 34-38, 40-48 and 50-66 are, thus, requested.

#### **Rejections under 35 U.S.C. § 103**

Claims 30-32 and 33-67 stand rejected under 35 U.S.C. § 103(a) as assertedly being unpatentable over Croy et al. in combination with Fromm et al. (Biotechnology, 1990, Vol. 8, pages 833-839). Applicants respectfully traverse the rejections as hereinafter set forth.

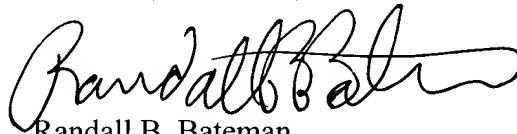
A *prima facie* case of obviousness cannot be established with regard to any of claims 30-32 or 33-67 since the cited references do not, alone or in combination, teach or suggest all of the limitations of any of the pending claims. As previously discussed herein, Croy et al. does not teach or suggest any of SEQ ID Nos. 1-7. Further, Fromm et al. does not teach or suggest the claimed sequences, *i.e.*, nucleic acids SEQ ID Nos. 1-7, nucleic acid sequences complementary to SEQ ID Nos. 1-7, or nucleic acid sequences having a degree of homology of more than 70% to SEQ ID Nos. 1-7 or the sequence complementary to SEQ ID Nos. 1-7. Since the cited references do not teach or suggest each and every limitation of any of claims 30-32 and 33-67, a *prima facie* case of obviousness has not been established.

Accordingly, reconsideration and withdrawal of the obviousness rejections of claims 30-32 and 33-67 are requested.

### CONCLUSION

In view of the foregoing amendments and remarks, applicants respectfully submit that the claims define patentable subject matter. If any questions remain after consideration of the instant amendments, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,  
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Attachments: Bundock et al., Integration of *Agrobacterium tumefaciens* T-DNA in the *Saccharomyces cerevisiae* genome by illegitimate recombination  
de Groot et al., *Agrobacterium tumefaciens*-mediated transformation of filamentous fungi